



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 4 :  A61M 5/32	A1	(11) International Publication Number: WO 87/ 07162  (43) International Publication Date: 3 December 1987 (03.12.87)
(21) International Application Number: PCT/AU87/00153 (22) International Filing Date: 27 May 1987 (27.05.87) (31) Priority Application Number: PH 6157 (32) Priority Date: 29 May 1986 (29.05.86) (33) Priority Country: AU (71)(72) Applicants and Inventors: THURECHT, Lola, June [AU/AU]; 5 Carslaw Street, Chifley, ACT 2606 (AU). LENFERINK, Josephina, Christina, Maria [AU/AU]; 33 Embley Street, Holder, ACT 2611 (AU). (74) Agents: DUNCAN, Alan, David et al.; Davies & Collison, 1 Little Collins Street, Melbourne, VIC 3000 (AU).		(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.  Published With international search report.
(54) Title: PROTECTIVE DEVICES FOR CANULAS  (57) Abstract <p>A protective device for a canula (13, 53) consists of a generally tubular sheath (10, 50) which has a slot (16, 56) extending from one end of it. The sheath (10, 50) completely covers the canula. The slot (16, 56) is wider than the outside diameter of the canula, so that the sheath can be removed from, and replaced over, the canula without the hands of the user of the canula being close to the tip of the canula. The sheath may be connected by a strap (18, 58) to a cap (20) or ring (54) which is fitted over the support for the canula.</p> <div data-bbox="1023 1155 1299 1932"> </div>		

*FOR THE PURPOSES OF INFORMATION ONLY*

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	ML	Mali
AU	Australia	GA	Gabon	MR	Mauritania
BB	Barbados	GB	United Kingdom	MW	Malawi
BE	Belgium	HU	Hungary	NL	Netherlands
BG	Bulgaria	IT	Italy	NO	Norway
BJ	Benin	JP	Japan	RO	Romania
BR	Brazil	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	LI	Liechtenstein	SN	Senegal
CH	Switzerland	LK	Sri Lanka	SU	Soviet Union
CM	Cameroon	LU	Luxembourg	TD	Chad
DE	Germany, Federal Republic of	MC	Monaco	TG	Togo
DK	Denmark	MG	Madagascar	US	United States of America
FI	Finland				

BEST AVAILABLE COPY

- 1 -

TITLE: PROTECTIVE DEVICES FOR CANULASTECHNICAL FIELD

This invention concerns the protection of the tips of the canulas (commonly called needles) used in hypodermic syringes and in the equipment used to take blood samples and donations.

BACKGROUND ART

It has long been recognised that a person who uses a hypodermic syringe or a canula at the end of a tube (for example, to administer a drug, to extract a blood sample or blood donation, to supply a drip to a patient or to effect a blood transfusion) is at some risk when the tip of the canula is exposed at the conclusion of the action being taken. The risk arises because the viruses for some diseases, notably hepatitis B and acquired immune deficiency syndrome (AIDS), are carried by the blood, and if the tip of a sharp needle (canula) containing even a very small sample of the blood of an infected person punctures the skin of the person handling the canula, that person handling the canula can become infected. So great is this risk to nurses, nursing sisters, doctors, paramedical personnel and laboratory staff that it is standard practice to cover the end (tip) of a canula immediately after use.

- 2 -

The covering of the end of a canula is effected with a cap or cover. Examples of protective caps have been described in the specification of U.K. patent No 1,514,725 and in the specifications of U.S. 5 patents Nos 4,248,246 and 4,629,453. The cap or cover is normally positioned over the end of the new and sterile canula, is removed prior to the use of the canula, and is then replaced after the canula has been used. Unfortunately, the cap or cover usually 10 has a small aperture into which the end of the canula must be fitted and it is not uncommon (even when a protective flange is fitted to the cover, as in the case of the invention of U.S. patent No 4,629,453) for the user of the canula to experience some 15 difficulty in aligning this aperture with the end of the canula, and for the user to be pricked by the canula in the course of attempting to cover its tip.

Factors such as improper room illumination, poor eyesight, lack of co-ordination or concentration, and 20 working under stress are likely to cause problems when a person has to guide the canula tip into the small aperture in the over. In a hospital, when a member of the nursing staff accidentally punctures his or her skin with a potentially contaminated 25 canula, the accident has to be reported as there may be a subsequent compensation claim if a serious and possibly incurable and/or fatal disease is contracted. The reporting requires the completion of

- 3 -

substantial documentation by the person who has been pricked by the needle, additional expenditure in administration and a general loss of productivity.

DISCLOSURE OF THE PRESENT INVENTION

5 It is an object of the present invention to overcome this disadvantage of the prior art protective covers for canulas.

This objective is achieved by providing a cover for a canula that is removeable from and replaceable over  
10 the canula without the need for the user of the canula to be in close proximity to the tip of the canula. The cover for the canula comprises a generally tubular sheath which is adapted to fully cover the canula and which is provided with an  
15 elongate slot through which the canula can pass. The provision of this slot enables the sheath to be moved laterally away from the canula to expose it for use, and enables the operator to restore the sheath to its protective position after the canula has been used,  
20 without the operator's hands having to be close to the tip of the canula.

Thus, according to the present invention, there is provided a protective device for a canula, said device comprising an elongate, substantially rigid,  
25 tubular sheath adapted to fit over the entire canula, characterised in that

BEST AVAILABLE COPY

- 4 -

- a) the sheath has an elongate slot formed therein and extending from one end thereof for at least part of the length thereof, the slot having a width which is greater than the diameter of the canula; and
- 5 b) said one end of the sheath is adapted to fit on to the support for the canula.

The support for the canula may be the conventional needle support of a hypodermic syringe or the end of  
10 a blood sampling flexible tube, in which case it is preferred that an annular retaining member, adapted to securely grasp said one end of the sheath, is fitted over the support for the canula.

Alternatively, the support for the canula may be  
15 provided with a cap which is firmly affixed (usually by manual pressure) over or into the end of the support for the canula, this cap having an aperture therein through which the canula projects. The end of the sheath which is remote from the tip of the  
20 canula (that is, the end of the sheath from which the slot extends) will then be a press fit over or into this cap.

The sheath and the annular retaining member (or the cap) may be connected by a short strap or cord, or a  
25 hinge, which ensures that the sheath remains connected to the needle support while the canula is used, thus preventing misplacement of the protective

- 5 -

sheath by the user of the canula. In this case, the length of the slot in the sheath will be approximately equal to the length of the canula.

Embodiments of the present invention will now be described, with reference to the accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective sketch of the present invention.

10 Figure 2 is a sectional view of an annular retaining member that may be used to secure the device of Figure 1 around a canula.

Figure 3 shows an alternative embodiment of the present invention fitted to a hypodermic syringe.

15 Figure 4 illustrates the removal and replacement of the protective sheath of the device illustrated in Figure 3.

Figure 5 is a perspective sketch of another embodiment of the present invention.

#### 20 DETAILED DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

The protective device illustrated in Figure 1 comprises a substantially rigid tubular member 10 which is tapered towards a closed end 11 and has an open end 12 which is adapted to fit over or into a

- 6 -

support for a canula. The tubular member 10 has a slot 16 extending from the end 12 for a distance which, in the illustrated embodiment, is substantially equal to the length of the canula that it protects. The slot has a width which is at least slightly greater than the outside diameter of the canula. The tubular member 10 may be made from any suitable material which is rigid enough to be self supporting in the configuration illustrated in Figure 1. A number of plastics materials meet this requirement.

Preferably, the end 12 of the protective device illustrated in Figure 1 is firmly held in its protective position around a canula by an annular retaining member which fits on to the needle support. One form of retaining member is illustrated in Figure 2.

The retaining member 17 of Figure 2 is moulded as a single article from a resilient material, such as neoprene or a flexible and resilient plastics material. It comprises an annular body portion 14 from which an arm 15 extends. The arm 15 is generally C-shaped in cross-section, with the top of the "C" defining a circular aperture that is greater in diameter than the internal diameter of the body section 14.



- 7 -

When the protective sheath 10 is placed over a needle mount on to which the retaining member 17 has been affixed, the end 12 deforms the circular end of the C-shaped arm 15 to force the top of the arm 15 outwards to permit the end 12 to bear against the top of the body portion 14. In this position, the resilient nature of the material from which the retaining member has been fabricated causes the arm 15 to revert, as far as possible, to its undeformed position, and thus to clamp the sheath 10 in the protective position, surrounding a canula.

To remove the tubular member 10 from its protective position around a canula, the tubular member is detached from the needle support on which it is mounted by a manual force applied at or near end 12 of the tubular member 10. After being detached from the needle support, the tubular member 10 is moved a distance away from the needle support until the tip of the canula can be passed through the slot 16. A sideways movement of the tubular member 10 (as shown in Figure 4, which is discussed below) enables the whole of canula to pass through the slot 16 as the tubular member 10 is removed. Replacement of the protective tubular member 10 is by the reverse of this sequence of steps.

When the retaining member 17 of Figure 2 (or a similar retaining device) is used to clamp the sheath 10 in its protective location, the force needed to

- 8 -

prise sheath 10 out of the grip of the retaining member will be greater than when a retaining member of this type is not used.

The retaining member may be connected to the sheath 5 10 by a flexible strap, if desired, to prevent the removal of the sheath from the region of the canula.

A variation of the combination of the protective sheath 10 of Figure 1 and the retaining member 17 of Figure 2 is illustrated in Figures 3 and 4. In the 10 embodiment of Figures 3 and 4, a cap 20 is a tight fit over the needle support. The cap 20 has an aperture in it to permit the canula 13 to project through the cap. The end of the sheath or tubular member 10 is a tight fit over the cap 20, and is 15 removed from cap 20 in the same way as the tubular member 10 of Figure 1 is removed from its associated needle support or retaining member 17.

There are some optional - but preferred - features in the embodiment illustrated in Figures 3 and 4. These 20 are

- a) the provision of a flexible strap 18 extending between a thickened region 19 of the tubular member 10 and the cap 20, to prevent the protective tubular member from being removed from 25 the syringe assembly and possibly misplaced while the syringe is being used; and

- 9 -

- b) a series of flutes or ridges 21 to facilitate the holding of the tubular member 10 between the fingers of a user of the protective device when the canula is being passed through slot 16 during the removal or the replacement of the tubular member 10.

The protective devices shown in Figures 1, 2 and 3 are designed to be moulded as a single item from a suitable plastics material.

- 10 Figure 5 illustrates another embodiment of the present invention, consisting of a tapered, tubular sheath 50 having a slot 56 formed in it. A thickened end region 59 of the sheath 50 has a strap 58 affixed to it. Strap 58 connects the region 59 to a ring 54  
15 which is adapted to be a tight fit over a support 55 for a canula 53 (shown in dashed outline to illustrate the way in which this embodiment of the invention is used). Flutes or ridges 57 assist in the manual gripping of the sheath 50. The operation  
20 of the embodiment of Figure 5 is essentially the same as the operation of the embodiment of Figures 3 and 4, and further explanation thereof is not necessary. The combination of sheath 50, strap 58 and ring 54 is designed to be moulded as a single item from a  
25 suitable plastics material, in which case the strap 58 will apply a bias to the sheath or cover 50 into the position shown in Figure 5. In this position, the cover will not interfere with the use of the canula to administer a drug or take a blood sample.

- 10 -

It will be clear that all the protective devices illustrated and described above are suitable for use with canulas (needles) mounted in syringes and in the ends of tubes, whether for administering a drug or a  
5 drip, or for taking samples of blood or other liquid from a human or animal body or from a storage container of blood or other liquid. The present invention may also be adapted for use with catheters and other body probes if protection against contact  
10 with the ends of such probes is required.

It will also be apparent that although specific realisations of the present invention have been illustrated and described, modifications of those  
15 embodiments can be made without departing from the present inventive concept.

BEST AVAILABLE COPY

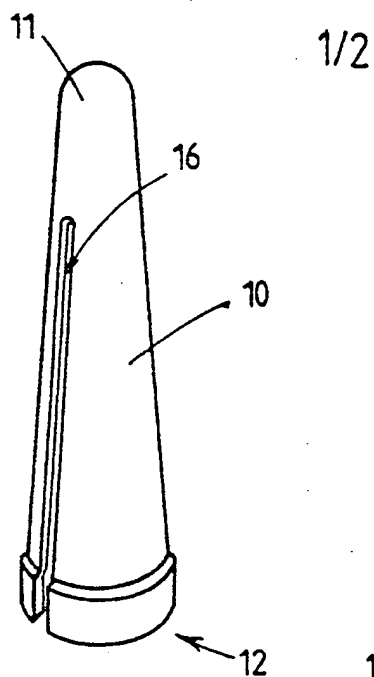
- 11 -

CLAIMS:

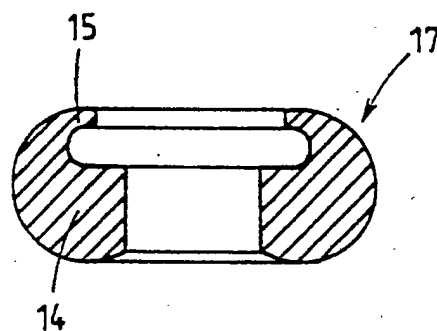
1. A protective device for a canula (13, 53), said device comprising an elongate, substantially rigid, tubular sheath (10, 50) adapted to fit over the entire canula, characterised in that
  - a) the sheath has an elongate slot (16, 56) formed therein and extending from one end (12, 59) thereof for at least part of the length thereof, the slot having a width which is greater than the diameter of the canula; and
  - b) said one end (12, 59) of the sheath (10, 50) is adapted to fit on to the support for the canula.
2. A protective device as defined in claim 1, in which an annular retaining member (17) is fitted over the support for the canula and said one end of the sheath (10) is adapted to be securely connected to said annular retaining member.
3. A protective device as defined in claim 2, in which said annular retaining member (17) has a body portion (14) from which an annular arm (15) of C-shaped cross-section extends, said annular arm (15) being adapted to grasp said one end of the sheath (10).

- 12 -

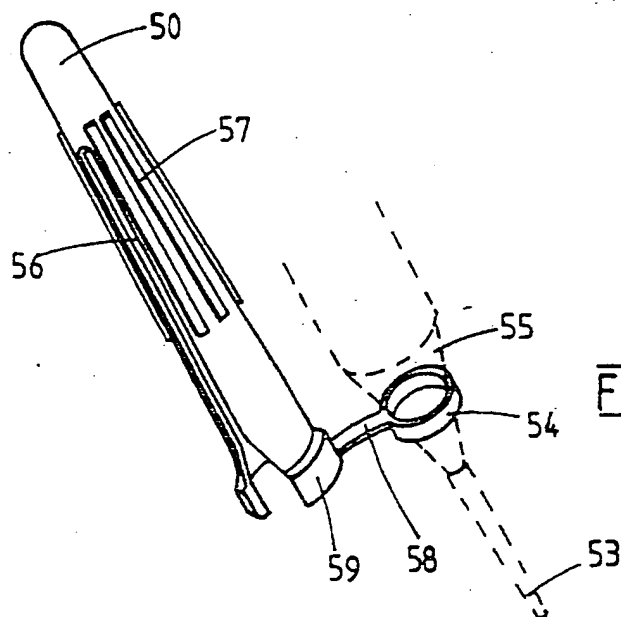
4. A protective device as defined in claim 1, in which a cap (20) is affixed to the support for the canula and said sheath (10) is adapted to be connected to said cap.
5. A protective device as defined in claim 4, in which said cap (20) and said one end (12) of said sheath are connected by a flexible strap (18).
6. A protective device as defined in claim 1, including a ring (54) which is a tight fit over the support for the canula, and a flexible strap (58) connects said ring (54) to said one end (59) of said sheath (50).
7. A protective device as defined in any preceding claim, including a plurality of flutes or ridges (21, 57) extending longitudinally on the surface of said sheath.
8. A protective device for a canula, substantially as hereinbefore described with reference to the accompanying drawings.



**FIG 1**



**FIG 2**



**FIG 5**

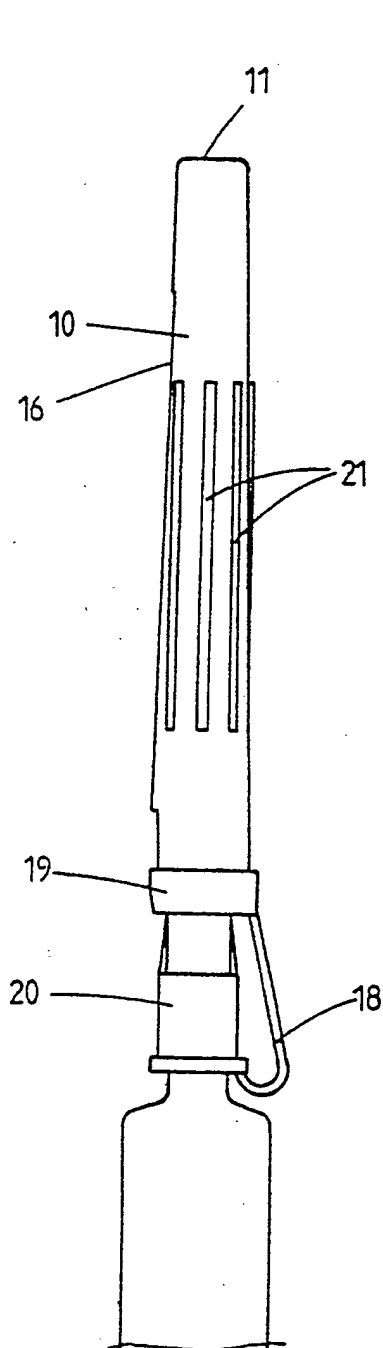


FIG 3

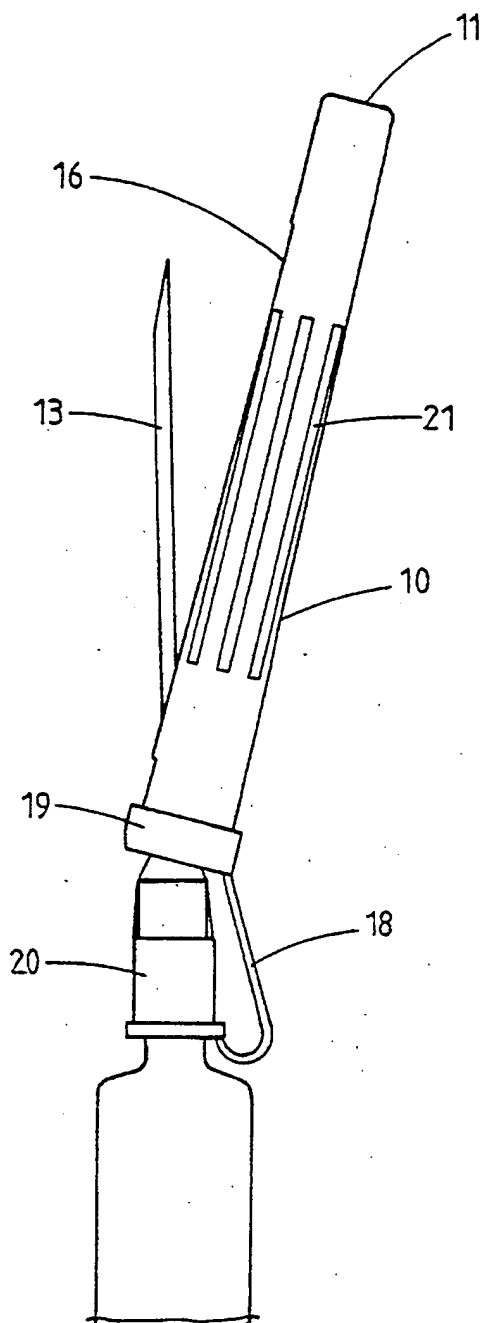


FIG 4



# INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 87/00153

<b>I. CLASSIFICATION &amp; SUBJECT MATTER</b> (If several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int. Cl <sup>4</sup> A61M 5/32		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched *		
Classification System	Classification Symbols	
IPC	A61M 5/32	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched *		
AU : IPC as above		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT*</b>		
Category *	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
X	US,A, 3658061 (HALL) 25 April 1972 (25.04.72) whole document	1-7
P,X	US,A, 4643722 (SMITH) 17 February 1987 (17.02.87) figures 3-10, Claim 18	1-4,7
X	US,A, 2110123 (EISELE) 8 March 1938 (08.03.38) figures 1-8	1
P,A	US,A, 4631057 (MITCHELL) 23 December 1986 (23.12.86)	
<p>* Special categories of cited documents: <sup>10</sup></p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
9 September 1987 (09.09.87)	(18.09.87) 18 SEPTEMBER 1987	
International Searching Authority	Signature of Authorized Officer	
Australian Patent Office	A HENDRICKSON	

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers ..... because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim numbers ..... 8 ..... because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically

the claim is not in accord with Rule 6.2(a)

3. ☐ Claim numbers ..... because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON  
INTERNATIONAL APPLICATION NO. PCT/AU 87/00153

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Members
JP 62144666	US 4631057

END OF ANNEX